REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claim 31 has been amended. The amendment to claim 31 is supported by the original disclosure, for example by page 28, lines 18-19. Claims 1-2, 4-11 and 13-31 are pending. No new matter has been added.

Claim rejections - 35 U.S.C. § 112

Claims 1, 2, 4-11 and 13-31 are rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The rejection contends that "free" is not supported by the specification. However, page 3 of the specification clearly describes the problem that if a saccharide such as glucose and any of various amino acids are administered via an intravenous drip or the like, a glycated amino acid increases temporarily. One of ordinary skill in the art would clearly understand from this description that the problem being identified is that the individual or free amino acids that are present in the intravenous drips become glycated and interfere with the measurement of the glycated protein. The method of claim 1 aims to address this problem by removing the individual or free amino acids that have become glycated as contaminants before measuring the glycated protein. Accordingly, the specification conveys to those skilled in the art that the Applicants were in possession of the claimed subject matter as recited in claim 1. Therefore, claim 1 and its dependent claims comply with the written description requirement.

Claim 31 is rejected under 35 USC 112, second paragraph, as being indefinite. Claim 31 recites that the hydrogen peroxide is removed using a catalase. Withdrawal of the rejection is requested.

Claim rejections - 35 U.S.C. § 103

Claims 1, 2, 4-11 and 13-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP1 002874 A2 (Komori et al.) in view of Eur. J. Biochem., 1996, Vol. 242, pp. 499-505 (Yoshida et al.) and US Patent No. 6,127,138 (Ishimaru et al.) and further in view of Biochemistry, 1988, Vol. 27, pp. 5470-5476 (Montellano et al.) and of US Patent No. 5,556,788 (Kwan et al.) and of J. Nutr., 1982, Vol. 112, p. 1631-1637 (Fry et al.). Applicants respectfully traverse this rejection.

The rejection refers to page 2, paragraphs 0002-0004 and page 4, paragraphs 0029-0030 and contends that Komori teaches a method of measuring an amount of a glycated

protein as an analyte in a sample, comprising: causing a FAOD to act on a glycated amino acid present in the sample so that the analyte remains in the sample. However, Komori does not teach or suggest this feature at page 2, paragraphs 0002-0004 and page 4, 0029-0030.

In particular, the discussion at page 2, paragraphs 0002-0004 and page 4, paragraphs 0029-0030 merely describes what is known. That is, Komori teaches that a protease is used first to degrade the glycated protein in the sample. One of ordinary skill in the art would understand that since FAODs are unable to oxidize proteins directly, the enzymatic measurement of the glycated proteins must be preceded by a proteolytic digestion to liberate the glycated amino acids within the proteins. The FAODs that are subsequently added cause the oxidative deglycation of the glycated amino acid to produce glucosone, the deglycated amino acid and hydrogen peroxide. Komori is silent as to whether the FAOD can be added before the protease treatment so as to allow the FAOD to act on a glycated amino acid present in the sample and thereby degrade the glycated amino acid, while allowing the glycated protein (analyte) that is to be measured to remain in the sample so that the amount of the glycated protein can be measured later.

In fact, at the time the present invention was made, it was commonly understood in the art of enzymatic measurements with FAODs that the addition of the protease prior to the addition of the FAOD would deactivate the activities of the FAOD for the measurement of the hydrogen peroxide. Therefore, given this understanding, one would not expect from the teachings of Komori that the glycated proteins could be measured if the FAODs were added before the addition of the protease. Komori does not provide any guidance or any experimental data showing that the FAODs would be functional if they were added prior to the addition of the protease. Accordingly, Komori merely teaches that the glycated protein (analyte) is degraded by the protease at the time the FAOD is allowed to act on the glycated amino acid, and is far from teaching or suggesting that the FAOD can act on the amino acid while the glycated protein (analyte) remains in tact so that the glycated protein (analyte) can be later degraded by the protease and the amount of the glycated protein can be measured using a measurement FAOD.

Yoshida, Ishimaru, Montellano, Kwan and Fry do not remedy the deficiencies of Komori. Yoshida teaches the use of FAODs that exhibit activities towards fructosyl-$^{\alpha}$N-valine and/or fructosyl-$^{\varepsilon}$N-lysine, the activities being the oxidative deglycation of fructosyl-

$^{\alpha}$N-valine and/or fructosyl-$^{\varepsilon}$N-lysine to produce glucosone, valine and/or lysine and hydrogen peroxide. However, Yoshida likewise merely teaches known enzymatic measurement methods using the FAODs, and fails to provide any guidance or experimental data to show that the glycated proteins could be measured if the FAODs were added before the addition of the protease.

Ishimaru teaches the use of catalase in a color developing reaction to measure the amount of the hydrogen peroxide. Montellano teaches the use of an azide ion to inhibit the catalase activity. Kwan teaches the conditions for the use of a tetrazolium compound and sodium azide in a solution. Fry teaches the formation of glycated amino acids in nutritional products. However, Ishimaru, Montellano, Kwan and Fry are silent as to the use of protease, and do not provide any reason to expect that an FAOD could be added so that a free amino acid that is glycated present in the sample as a contaminant is degraded and removed from the sample by the FAOD while the glycated protein remains in the sample, as recited in claim 1. Accordingly, even when combined, the references fail to meet the features of claim 1. Therefore, claim 1 and its dependent claims are patentable over the references taken alone or together.

The rejection contends that once the method of measuring an amount of glycated protein in an analyte was established, providing a measuring kit of claim 9 to determine the amount of the glycated protein would become obvious in view of Ishimaru et al. However, as discussed above, the references fail to provide any reason to expect that the glycated proteins could be measured if the FAODs were added prior to the addition of the protease. Accordingly, claim 9 and its dependent claims are patentable over the references, taken alone or separately.

In view of the above, favorable reconsideration in the form of a notice of allowance is requested. Any questions or concerns regarding this communication can be directed to the attorney-of-record, Douglas P. Mueller, Reg. No. 30,300, at (612) 455.3804.

Respectfully submitted,

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